Remarks

Claims 48 and 70-80 are pending upon the entry of the amendments made in this paper.[1] Claim 48 is amended to remove the recitation that the composition is "solid" and "suitable for oral administration," and to recite the amount of descarboethoxyloratadine ("DCL") of 0.1 to 10 mg. Support for these amendments can be found, for example, on page 17, lines 9-12 and Examples 7-9 of the specification.

Claim 70 is amended to remove the recitation that the composition is adapted for administration "in a single dose per day," and to add the recitation that the composition is adapted for "oral" administration, the subject matter which is removed from claim 48. New claim 72 is added to recite, in part, the "solid" pharmaceutical composition, also the subject matter which is removed from claim 48. Support for the claims as amended is found in the specification and claims as originally filed, for example, on page 16 of the specification.

New claims 73-80 are added to recite, in part, pharmaceutical compositions comprising DCL and specific carriers. Support for these claims can be found, for example, in Examples 7-9 of the specification. No new matter has been added.

Applicants respectfully submit that all of the pending claims are allowable for at least the following reasons.

A. The Indefiniteness Rejection Should Be Withdrawn

On page 2 of the Office Action, claims 48 and 70-71 are rejected as allegedly indefinite. In particular, it appears that the Examiner alleges that the claims are indefinite because they do not specifically define "the ratio or quantitative relationship" of 5 mg DCL and other ingredients[2]. Applicants respectfully point out that in view of the amendments made in this paper, this rejection is now moot.

Claim 48, which recites, in part, a solid pharmaceutical composition which comprises 0.1 to 10 mg of DCL and a pharmaceutically acceptable carrier, is clear and

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[1] No additional claim fees are believed to be due because fees for 33 claims, including 3 independent claims, were originally paid in this application. Should additional fees be required, please charge the fees to deposit account no. 503013.

[2] First, Applicants respectfully point out that claim 48 as amended does not recite "5 mg" DCL. Second, while it is alleged in the Office Action that "the term 'adapted for administration in a single dose per day' lacks antecedent basis in the specification," claims as amended do not recite such a limitation.

unambiguously described in the specification. In fact, the claimed pharmaceutical composition recites a required amount of DCL, the active ingredient, and provides that a carrier, *e.g.*, a pharmaceutical excipient, also be present in the composition. Therefore, the claim is both clear and uses common place terms and format.

Further, the specification provides several exemplary compositions which comprise 0.1 to 10 mg DCL and various carriers. Thus, especially when read in light of the specification, there is little doubt that the claim "ha[s] a meaning discernible to one of ordinary skill in the art when construed according to correct principles," and Applicants respectfully submit that nothing more is required.[3] (*Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings*, 370 F.3d 1354, 1366 (Fed. Cir. 2004)). Therefore, Applicants respectfully submit that claims 48 and 70-71 are definite and request that the rejection of the claims under 35 U.S.C. § 112, ¶2 be withdrawn.

B. The Written Description Rejection Should Be Withdrawn

On pages 2-3 of the Office Action, claims 48 and 70-71 are rejected as allegedly failing to comply with the written description requirement. In particular, it is alleged that "[t]he specification lacks antecedent basis for the scope of solid pharmaceutical composition compris[ing] 5 mg [of DCL]," or for "single dose per day" administration. (Office Action, page 2). Applicants respectfully traverse this rejection.

Applicants respectfully submit that the specification does indeed provide adequate disclosure for the "composition comprising 5 mg of DCL." Indeed, the Examiner points to the portions of the specification which provides support for the doses of 0.1 to 10 mg, 0.1 to 5 mg, and 0.1 to 2 mg of DCL."[4] (*See* Office Action, page 3).

However, solely to expedite the prosecution of this application, claim 48 is amended herein to recite, in part, a pharmaceutical composition comprising 0.1 to 10 mg

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[3] Indeed, claiming a pharmaceutical composition "comprising a specific amount of an active ingredient and pharmaceutically acceptable carrier," with no other limitations, is a common practice. (*See, e.g.*, U.S. Patent Nos. 7,078,398 and 5,712,302, copies of which are attached hereto as **Exhibits A and B**).

[4] Applicants also point out that the limitation of "single dose per day" is also supported by the specification since the same portion further points to the specific recitation of "administration in single or divided doses. However, solely to expedite the prosecution of this application, that limitation is removed from claim 70. Thus, the issue is now moot and therefore is not addressed herein.

DCL.[5] The recited range is expressly supported by the specification and the claims as originally filed. (*See*, *e.g.*, page 17, lines 9-12 and Examples 7-9 of the specification). In view of this amendment, Applicants respectfully request that the rejection of the claims under 35 U.S.C. § 112, ¶1 be withdrawn.

C. The Enablement Rejection Should Be Withdrawn

On pages 3-4 of the Office Action, claims 48 and 70-71 are rejected as allegedly not enabled. In particular, it is alleged that the claims are not enabled based on the Examiner's assertion that the specification would be "considered guiding one skilled in the art to use multiple dosage units of the most preferred oral dose composition in units about 0.2 mg to about 1 mg to achieve the required daily dose range which should be about 0.1 mg to about 5 mg." (Office Action, page 3). It is further alleged that the specification does not provide "enablement for a single unit oral dosage form in 5 mg per unit dose with efficacy in maintaining serum concentration." (*Id.*, page 4).

Although Applicants respectfully disagree with each of these allegations, claim 48 is amended to recite, in part, a pharmaceutical composition comprising 0.1 to 10 mg of DCL. Thus, the claim requires a pharmaceutical composition comprising a specific amount (0.1 to 10 mg) of a specific active ingredient (DCL). In addition, examples of compositions comprising 0.1 to 10 mg of DCL are provided in Examples 7 to 9 of the specification. Accordingly, no undue experimentation, indeed hardly no experimentation at all, would be required for those skilled in the art to make and practice the claimed composition since all that is required is to employ the specified compound in the specified amount, both of which are described in the specification, in a pharmaceutical composition, examples of which are shown in the specification. Utility for the composition, *e.g.*, diseases to be treated, is also clearly provided in the specification. Therefore, since it is clear that "one reasonably skilled in the art could make or use [the claimed composition] from the disclosures in the patent coupled with information known in the art without undue experimentation," Applicants respectfully submit that the claims are enabled. (*United States v. Telectronics, Inc.*, 857 F.2d 778, 785 (Fed. Cir. 1988)).

[5] This amendment is made partly because "5 mg" DCL is fully encompassed by the range of "0.1 to 10 mg" DCL.

Further, with regard to the allegation that the specification does not enable "a single unit oral dosage form in 5 mg[6] per unit dose with efficacy in maintaining serum concentration," Applicants respectfully point out that no showing of "efficacy in maintaining serum concentration" is required for the description to be enabling for the claimed composition. Moreover, the claims have been amended such that this rejection is moot.

Nevertheless, Applicants also submit herewith a copy of the package insert of Clarinex®, which post dates the priority of the instant invention (attached hereto as **Exhibit C**). The insert shows that Clarinex® is a composition comprising 5 mg of DCL as an active ingredient, and that 5 mg DCL once a day is effective (*i.e.*, the recommended dose is 5 mg once a day). Therefore, in view of this additional evidence, Applicants respectfully request that the rejection of the claims under 35 U.S.C. § 112, ¶1 be withdrawn.

D. The Rejection Under 35 U.S.C. § 103 Should Be Withdrawn

On pages 4-5 of the Office Action, claims 48 and 71 are rejected as allegedly obvious over U.S. Patent No. 4,659,716 to Villani ("Villani"). Applicants respectfully traverse this rejection.

Claim 48 recites, in part, a pharmaceutical composition comprising 0.1 to 10 mg of DCL. Villani does not disclose or suggest the claimed composition. Villani discloses a genus of compounds which encompasses DCL, although Applicants note that DCL is disclosed as an example. Furthermore, Villani discloses a very broad range of amount of active ingredient, *i.e.*, 1-1000 mg, that can purportedly be used in compositions. Therefore, Villani discloses a composition containing 1-1000 mg of DCL.[7]

Furthermore, Villani does not suggest the claimed composition because the specific compositions of DCL disclosed in Villani, *i.e.*, those disclosed in Examples E-I of Villani contain: 200 mg/g; 200 mg/g; 200 mg/g; 200 mg/g; and 100 mg/g of DCL,

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[6] Again, claim 48 as amended recite, in part, a pharmaceutical composition comprising 0.1 to 10 mg of DCL.

[7] Applicants respectfully point out that Villani even falls short of disclosing such a composition. This is because, while DCL is disclosed as an exemplary compound, Villani makes it clear that its preferred compound is not DCL. (*See* Villani, column 11, lines 21-23).

respectively. These amounts are significantly higher than the amounts recited by the pending claims.

Therefore, with respect to compositions, Villani only discloses a broad range of amount (*i.e.*, 1-1000 mg), along with several exemplary compositions containing an amount of DCL much higher than 0.1 to 10 mg. While no description whatsoever of a specific unit dose of 0.1 to 10 mg is provided in Villani, Applicants note that Villani alleges that the compounds it discloses may be administered, for example, in an amount of 10-20 mg per day in two to four divided doses. (*See* Villani, col. 11, lines 24-33). This disclosure may arguably be interpreted to suggest a range of doses, which the Examiner appears to suggest may overlap with the dosage form or composition that is claimed. However, when combined with the disclosures of a much broader general range and exemplary compositions containing much higher amount of DCL in connection with compositions, Villani cannot be fairly read to disclose or suggest the presently claimed invention. (*See generally In re Arkley*, 455 F.2d 586 (C.C.P.A. 1972)). For this reason alone, Applicants respectfully submit that no *prima facie* case of obviousness is established by Villani, and thus, request that the rejection be withdrawn.

In addition, even assuming, *arguendo*, that a *prima facie* case of obviousness were established by Villani, Applicants respectfully point out that sufficient unexpected results and/or teaching away are in the records to rebut any presumption of obviousness. For example, while no motivation to use DCL for the treatment of patients[8] was existed at the time of this invention due to the adverse effects known to be associated with the administration of compounds structurally similar to DCL (*e.g.*, loratadine and astemizole), the specification provides that DCL was unexpectedly found to have much reduced tumor promoting activity than loratadine. (*See* Applicants Response of August 12, 2005 and Storms Declaration submitted therewith; see also Tarantino Declaration, attached hereto as **Exhibit D**). In view of these unexpected results, Applicants respectfully submit that the rejection of the claims under 35 U.S.C. § 103 should be withdrawn.

[8] Although the current claims recite pharmaceutical compositions, the term "pharmaceutical composition" indicates utility in and administration to a patient.

E. Claims 73-80

Applicants respectfully submit that claims 73-80 are separately patentable in view of the prior art references in the record. As the Examiner will see, claims 73-80 additionally require that the claimed pharmaceutical composition comprise certain specific carriers, in addition to 0.1 to 10 mg of DCL, or a pharmaceutically acceptable salt thereof. For the reasons stated above, Applicants believe that the claims which recite 0.1 to 10 mg of DCL, without reciting the specific carriers, are patentable. Thus, claims 73-80, which do recite certain specific carriers, are further removed from the prior references in the record. In the case that the Examiner finds claims 73-80 would be patentable, if rewritten in independent forms, the Examiner is respectfully invited to contact the undersigned by telephone.

F. Conclusion

For at least the foregoing reasons, Applicants respectfully submit all of the pending claims are allowable, and thus respectfully request the allowance thereof.

No fee is believed due for this submission. Should any additional fees be required for this submission or to avoid abandonment of the application, please charge such fees to Jones Day Deposit Account No. 503013.

Respectfully submitted,

Date October 10, 2006

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Hoon Choi (Ltd. Recog. No.)
Jones Day

For: Anthony M. Insogna (Reg. No. 35,203)
Jones Day
12750 High Bluff Drive Suite 300
San Diego, CA 92130
(858) 314-1200